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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/501,112
Filing Date: July 07, 2004
Appellant(s): BENKOWSKI ET AL.

David L. Terrell
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/6/10 appealing from the Office action mailed 8/6/09.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Withdrawal of the 102 rejection of dependent claims 3, 6, 10, and 27 in view of Medvedev et al.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2004/0152944	Medvedev et al	8-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 7-9, 11-15, 19, 24-26, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Medvedev et al (2004/0152944). Medvedev discloses that the pump speed is changed based on or in response to the diastolic flow rate (e.g. paragraphs 57-61, DQ) and based on the heart rate or pressure (e.g. abstract). In addition, the pump speed is set in accordance with activities, such as sleep, normal activity, or high-energy activity, since the heart rate or other sensed parameters will change in response to these activities affecting the speed of the pump. For claim 19, the system senses pressure through the three feedback waveforms and for claim 8, the system of Medvedev includes an implantable flow measurement device since the implantable device measures flow.

26. A method of controlling a blood pump implanted in a patient, comprising:	Medvedev discloses in the abstract (and throughout) the use of a microprocessor, 18, to control his implanted pump, 10.
monitoring the patient's blood pump flow rate;	Medvedev discloses in the abstract the current pump flow rate is determined.
extracting the patient's diastolic pump flow rate from the pump flow rate, wherein the diastolic pump flow rate is a separately isolated flow contribution below a mean flow rate; and	Medvedev discloses in paragraphs 55-64, and specifically paragraphs 59 and 68 that Qpeak(-) is the average of the peak minimum instantaneous flow rates and is associated with ventricular diastole and is plugged into the DQ equations. The DQ equations also use the mean flow rate, Qmean, and the peak and minimum flows are extracted/derived from the flow.
changing a speed of the pump in response to the extracted diastolic pump flow rate.	Medvedev discloses in paragraphs 57 and 60 that DQ, which uses the diastolic pump flow rate Qpeak(-), is used to change pumping power and therefore pumping speed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Medvedev et al. Medvedev discloses the claimed invention except for sensing of diastolic flow rate from the sensed pressure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable pump and method as taught by Medvedev, with the sensing of diastolic flow rate from the sensed pressure since it was known in the art/the examiner is taking official notice that implantable pumps and methods use the sensed pressure to determine diastolic flow rate to provide the predictable results of a conventional way to easily determine the flow rate from sensed pressure without using other flow sensors.

(10) Response to Argument

iv. Claims 1 and 26

The applicant argues that Medvedev does not contain the claim limitations of "extracting the patient's diastolic pump flow rate from the pump flow rate" and "wherein the diastolic pump flow rate is a separately isolated flow contribution below a mean pump flow rate". These

arguments are not persuasive. Medvedev states in paragraph 68 that "[D]erived from equation 4, the steady state power-flow curves can be used for mean, peak, and minimum pump flow calculations" and therefore provides for an "extraction". Extract is defined as "to draw forth (as by research) <extract data>" and "to determine (a mathematical root) by calculation" (http://www.merriam-webster.com/dictionary/extract) and "pull something out" or "obtain something from a source" (Encarta World English Dictionary). In addition, Medvedev states that Qpeak(-) is the average of the peak minimum instantaneous flow rates within each cardiac cycle, where the peak minimum flow is associated with ventricular diastole (para. 59) and therefore since the peak and minimum pump flow calculations are derived from the flow calculation of equation 4, Medvedev provides for the extraction of the diastole flow rate, Qpeak(-) from the pump flow rate.

Medvedev also states in paragraph 33 that the "instantaneous flow waveform can be employed to find the pump mean flow" and in paragraph 58 that flow pulsatility, DQ, uses specific variables, such as Qpeak(-) and Qmean to calculate DQ. Medvedev necessarily "extracts" and "isolates" the diastole Qpeak(-) and Qmean from the flow rate since these represent the average of the peak minimum instantaneous flow rate and the mean flow rate and are plugged into the DQ equations (i.e. each Qpeak(-) and Qmean are separate numbers that are plugged into the DQ equation and are therefore isolated). To determine the minimum or mean of a flow, you must know the flow rate and take/extract the minimum and mean. In addition, the peak minimum flow is necessarily a flow contribution below a mean pump flow since the minimum, Qpeak(-), is below a mean, Qmean, and since they are two separate values. The claim does not state that the diastolic pump flow rate is the entire amount or contribution below the

mean and the claim does not contain any active step to "calculating" the mean pump flow rate and "isolating" the entire flow contribution.

vi. Claim 4

The argument that Medvedev does not contain the claim limitation of increasing the pump speed in response to an increase in heart rate is not persuasive since Medvedev shows in figure 1 and describes in paragraphs 26-32 and throughout the specification that the pump flow rate (and therefore speed) is increased due to an increase in heart rate.

vii. Claim 7

The arguments that Medvedev does not contain a controller to "extract a separate diastolic pump flow rate" and does not contain an input for receiving a blood flow rate signal" are not persuasive. As discussed above in section "v." Medvedev does extract and separately isolate a diastolic pump flow rate. In addition, Medvedev does contain a controller, 18 in figure 6, that does receive inputs (e.g. output of elements 28 and into controller 18) of the flow rate sensor comprised of the current, power, and frequency components, 20, 14, 24 (e.g. paragraphs 46-48).

viii. Claim 8

The argument that Medvedev does not contain an implantable flow measurement device that outputs a flow rate signal is not persuasive since Medvedev's implantable system does calculate flow using the current, power, and frequency components, 20, 14, and 24 of the flow rate sensor and outputs a flow rate "signal". It is noted that the claim does not state the claimed flow rate measurement device actually calculates flow rate or that it is a single component, just that the "measurement device" outputs a flow rate signal. Sensors, in general, output a measured

signal and then another component, such as a controller, interprets that signal. In addition, measurement devices do not need to be solely one component, but do contain several components or sensed values to determine a particular value.

The applicant is correct that Medvedev does advocate that no "extra hardware inside the patient" be used (paragraph 5) such as an actual extra pressure or flow sensor placed inside the body, but that does not mean that Medvedev cannot contain a flow sensor using several components such as the current, power, and frequency components used to make up the flow sensor. Medvedev states in paragraph 66, "this brings all required sensing inside...and simplifies the system".

The applicant further argues specific advantages of his system and sensor and disadvantages of Medvedev's sensor on pages 15-17 of the brief. It is noted these advantages and disadvantages are not claimed.

x. Claim 12

The Applicant argues that Medvedev does not increase the speed of the pump in response to an increase in the heart rate. This is not persuasive as discussed above in argument vi.

xi. Claim 19

The Applicant argues that Medvedev does not contain a pressure sensor for providing pressure sensor data to the controller. This argument is not persuasive as discussed similarly above in argument viii. Medvedev may not have an extra hardware pressure sensor, but does calculate and contain a pressure sensor that provides "pressure sensor data" by using the current, power, and frequency signals (e.g. abstract, para. 48, etc).

C. Obviousness

iii. Claim 20

It is noted that the Applicant does not state the Examiner has not provided sufficient documentary evidence to support the official notice. It is argued that Medvedev never derives separate diastolic pump flow rate information, never breaks down his calculated flow, and teaches away from including an implantable pressure sensor. These arguments are not persuasive in view of the discussion above in sections iv. and viii. Medvedev may not contain an "extra" hardware sensor to be placed outside his housing in the blood, but Medvedev does contain a flow sensor (i.e. a device that detects flow) and contains a pressure sensor that provides the claimed "signals" or "data" sent to the controller.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/George R Evanisko/

Primary Examiner, Art Unit 3762

Conferees:

/Scott M. Getzow/

Primary Examiner, Art Unit 3762

/Greg Vidovich/

TQAS, TC 3700